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Assessing the minimally important difference in the Oral Impact on Daily Performances index in patients treated for periodontitis

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Abstract

Aim: To assess changes over time and determine the minimally important difference (MID) in the Oral Impact on Daily Performances (OIDP) index for patients with severe generalized periodontitis receiving periodontal treatment.

Methods: This study was nested in a larger randomized controlled trial and consisted of 45 consecutive subjects of the larger trial (17 receiving intensive and 28 receiving conservative periodontal care). The OIDP index assessed impacts on quality of life (QoL) at baseline and 1 month after treatment. Repeated-measures ANOVA was used for comparison over time and between treatment groups. To estimate the MID, two subjective global transition scales, related to periodontal and oral health, respectively, were used as anchors, whereas the effect size (ES), standardized response mean and standard error of measurement were also calculated.

Results: The mean OIDP score after treatment was significantly lower than at baseline, indicating improvement in QoL, but there were no differences between treatment groups. Based on an agreement between different methods, the MID of the OIDP index was around five scale points and corresponded to a moderate ES.

Conclusion: The MID for the OIDP index among patients treated for severe generalized periodontitis provides meaning to change scores and facilitates interpretation of findings.

Key words: minimally important difference; periodontal diseases; quality of life; responsiveness; treatment

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Patient-reported outcomes, such as oral health-related quality of life (OHRQoL) measures, have scarcely been used in relation to periodontal diseases. The few relevant cross-sectional studies on either clinical practice patients or community sample participants have shown that periodontal conditions have a negative impact on the quality of their lives (Needleman et al. 2004, Ng & Leung 2006, Cunha-Cruz et al. 2007, Lopez & Baelum 2007). Despite their limited use in periodontal research, such measures may provide valuable information in clinical practice, for example, for identifying treatment needs, selecting therapies, evaluating treatment outcomes and monitoring patient progress (Allen 2003, Locker 2004, Rozier & Pahel 2008). Although some clinical trials have reported that periodontal treatment resulted in significant improvement in patient's quality of life (Ozcelik et al. 2007, Aslund et al. 2008, Jowett et al. 2009), these reports provided no indication as to whether the improvement was clinically meaningful.

There are two potential reasons for the dearth of studies evaluating the effects of periodontal treatment on quality of life.

Conflict of interest and source of funding statement

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First, there are not many condition-specific (CS) OHRQoL measures that specifically assess the psychosocial impacts attributed to periodontal conditions. In contrast to generic OHRQoL measures, the restricted focus of CS-OHRQoL measures makes them potentially more responsive to small, but clinically important changes, in oral health (Allen 2003). Although there are several OHRQoL measures, the Oral Impacts on Daily Performances (OIDP) index is the only OHRQoL measure designed to link specific oral problems leading to the impacts on quality of life (Adulyanon & Sheiham 1997). Therefore, the OIDP index has been used to assess CS impacts attributed to dental caries, periodontal disease, malocclusion, dental trauma and missing teeth (Gherunpong et al. 2006, Tsakos et al. 2006, Bernabé et al. 2007, Ryu et al. 2008). Second, despite evidence supporting the validity of generic OHRQoL measures used to assess the effects of periodontal treatment, their ability to detect small but meaningful changes over time has not been evaluated. Without empirical evidence on responsiveness to change, and particularly on the ability to detect small meaningful changes, researchers cannot be sure whether any difference in the OHRQoL reflects actual change or merely measurement error (Guyatt et al. 1987, Locker 1998, Locker et al. 2004, Osoba & King 2005).

The minimally important difference (MID) is the smallest score or change in a score that would be important from the patient's or clinician's perspective (Guyatt et al. 2002, Revicki et al. 2006, 2008). Consequently, it is crucial to determine the MID for an OHRQoL measure to interpret whether the observed change is meaningful (Guyatt et al. 2002, Osoba & King 2005, Revicki et al. 2006, 2008, Copay et al. 2007). Two general approaches have been described to determine the MID: anchor-based methods and distribution-based methods. Anchor-based, or externally referenced, methods compare the change in OHRQoL scores to other subjective or objective measures of change, considered as an anchor or external criterion. Distribution-based, or internally referenced, methods compare the change in OHRQoL scores to some measure of variability, such as the standard error of measurement (SEM) or the effect size (ES) (Guyatt et al. 2002, Osoba & King 2005, Revicki et al. 2006, 2008, Copay et al. 2007). Currently, there is no consensus as to the best method for determining the MID. For any particular measure, it has been recommended to obtain a range of MID estimates by different methods, and then to triangulate, i.e. reach a consensus, on a single value or small range of values (Revicki et al. 2006, 2008).

At present, no periodontal disease intervention study has addressed the issue of responsiveness to change, let alone determine the MID in relation to periodontal treatment. Such information would make OHRQoL measures clinically more useful and relevant in their application to evaluating periodontal care. Therefore, the objectives of this study were to assess changes over time and determine the MID in the OIDP index for patients with severe generalized periodontitis receiving periodontal treatment.

Methods

Study design and procedures

This study was nested in a larger parallel arm, double-blind, randomized controlled trial to evaluate the effects of periodontal therapy on endothelial function over a 6-month period. The sample for this nested study consisted of 45 consecutive subjects that participated in the larger trial. They were recruited from the subjects referred for periodontal therapy to the Periodontology Unit of the Eastman Dental Hospital, by consecutively inviting those that met the entry criteria, namely, to have severe (probing pocket depths >6 mm and marginal alveolar bone loss $>30\%$) generalized (at least 50% of teeth affected) periodontitis (D'Aiuto et al. 2004). Subjects were excluded from the study if they had: (i) known systemic diseases (i.e. diabetes, cardiovascular, kidney, liver or lungs diseases), (ii) history and/or presence of any other acute or chronic infections as assessed by clinical examination and laboratory routine screening, (iii) systemic antibiotic treatment in the preceding 3 months, (iv) concomitant treatment with any medication, (v) hypersensitivity to tetracyclines, (vi) patients in need of antimicrobial coverage for dental procedures and (vii) pregnancy or lactating females. The methodology of the study was ethically approved by the Eastman/UCLH Joint Ethics Committee and all participants gave written informed consent. Full details of methods for the larger study are presented elsewhere (Tonetti et al. 2007).

On entry to the trial, a baseline detailed periodontal examination was performed by one clinician. After their baseline visit, subjects were randomized to two different periodontal therapy intervention groups: an intensive care group (ICG) and a more conservative care group (CCG). The randomization was carried out by the trial coordinator and was restricted through minimization (Altman & Bland 2005) by the study registrar to avoid an imbalance between the two groups with respect to smoking status, sex, age and severity of periodontitis. Allocation to the treatment was concealed and revealed to the therapist only on the day of treatment. While random allocation of subjects into the treatment groups was carried out in blocks for the larger trial, appointments were arranged according to the availability of subjects. In addition, cancelled appointments were re-arranged. This resulted in an unequal size of the two groups for this nested study, as it collected data on 45 patients with consecutive appointments from the larger trial. Therefore, the sample for this study consists of 17 subjects from the ICG and 28 subjects from the CCG.

Before their first treatment session, subjects were interviewed about their subjective perceptions to oral and general health, including the assessment of OHRQoL, by a different researcher in a separate room. Following the completion of their treatment regimen, subjects were recalled both for an interview (30 days after) and clinical examination (60 days after) using the same format as before the initial periodontal treatment.

The periodontal regimen for all participants included basic oral hygiene instructions. Then, CCG participants underwent a standard cycle of supragingival mechanical scaling and polishing, while ICG participants received full-mouth intensive subgingival scaling and root planing under local anaesthesia, followed by extraction of teeth that could not be saved and adjunctive local delivery of minocycline microspheres (Arestin®, OraPharma, Warminster, PA, USA).

Data collection

The interviewer-administered questionnaire collected data on basic socio-demographic variables such as age, sex and level of education, smoking habits, OHRQoL and subjective assessments of oral health transition. OHRQoL was assessed using the OIDP index (Tsakos et al.

2001). This is a composite measure that focuses on basic daily life activities (eating, speaking, cleaning teeth, doing light physical activities, going out, relaxing, sleeping, smiling, major work or role, emotional stability and social contact) and attempts to measure oral impacts that affect the person's daily life. For each of the aforementioned performances, if a respondent experienced an oral impact the frequency and severity of the effect were scored using five-point Likert scales. If no impact was experienced, then a zero score was assigned. Performance scores were estimated by multiplying the corresponding frequency and severity scores. The OIDP score was the sum of the performance scores multiplied by 100 and divided by the maximum possible score, therefore ranging from 0 to 100. Higher OIDP scores represent worse OHRQoL. In addition, the OIDP index is specifically designed to obtain information from the respondent on what specific oral conditions they associated with their oral impacts. This is expressed through the calculation of CS-OIDP scores for different oral conditions. Consequently, OIDP can be used both as a generic and a CS-OHRQoL measure (Sheiham & Tsakos 2007, Ryu et al. 2008, Bernabé et al. 2009b). The CS-OIDP detects the causal relations of the impacts, whereas the overall OIDP does not provide information on which dental condition has led to the impact. For example, high OIDP scores may be caused by different conditions, such as pain from dental caries, tooth mobility from periodontal disease or chewing difficulty from missing teeth; clearly, these require different kinds of treatments. Using the generic OIDP score would not differentiate between those options. For this study, we used both the generic OIDP score and the CS-OIDP score attributed to periodontal conditions.

The questionnaire administered to participants 1 month post-treatment contained also two subjective global transition scales, one in relation to periodontal health and the other covering oral health in general. For the former, participants were asked to state whether their periodontal health had changed since the completion of treatment at the clinic. They used a five-point Likert scale ranging from ''worsened a lot'' to ''improved a lot''. For the latter, a similar question was also asked in relation to their oral health in general. Clinical periodontal data were recorded at baseline by a single trained dental examiner, who was unaware of the treatment assignments. Details about the clinical periodontal measures have been reported (Tonetti et al. 2007).

Statistical analysis

First, we assessed the distribution of the variables used in the analysis. The whole sample and two treatment groups were described in terms of socio-demographic (age, sex and education), behavioural (smoking) and clinical characteristics (mean number of teeth present, mean probing pocket depth and mean number of pockets with probing depth >4 mm), as well as perception of oral impacts. Fisher's exact and Mann–Whitney tests were used to compare baseline socio-demographic, behavioural and clinical characteristics between patients who were lost to follow-up and those who completed the trial. All analyses were carried out on an intention-to-treat (ITT) basis. For ITT analysis, missing scores after treatment for the generic and CS-OIDP were imputed with their corresponding scores at baseline (i.e., last observation carried forward). Sensitivity analysis showed no differences between ITT and complete-cases analyses.

Change scores for the generic and CS-OIDP were calculated by subtracting the scores after treatment from the corresponding baseline scores. Therefore, positive scores indicated improvement and negative scores deterioration in OHRQoL. One-way repeated-measures ANOVA was used to compare the generic and CS-OIDP scores before and after treatment (within-group comparison) as well as between the two treatment groups (ICG *versus* CCG).

For the estimation of MID, we used both anchor- and distribution-based (also called externally and internally referenced, respectively) approaches (Osoba & King 2005, Revicki et al. 2006, 2008, Copay et al. 2007). For the anchor-based approach, we used the two global items on subjective periodontal and oral health transitions as the two external reference criteria. In this case, the MID refers to the mean generic and CS-OIDP change scores for patients who reported little improvement in each of these global ratings (Guyatt et al. 1987, Juniper et al. 1994). For the distribution-based approach, the ES, the standardized response mean (SRM) and the SEM for both the generic and the CS-OIDP were used (Osoba & King 2005, Revicki et al. 2008). Both the ES and the SRM are expressed as ratios, with the numerator being the mean change score (for both) and the denominator being the standard deviation of the baseline score (ES) or the change score (SRM). The ES and the SRM are expressed in standard deviation units and are conventionally interpreted through Cohen's (1988) benchmark values of small (0.2), moderate (0.5) and large (0.8) effect. The SEM, on the other hand, is defined as the variability between a patient's observed and true score and is calculated by multiplying the standard deviation of the baseline score with the square root of 1 minus the reliability of the OHRQoL measure (Wyrwich et al. 1999a, b). For interpretation, a change smaller than the SEM is the likely result of a measurement error (Copay et al. 2007). Therefore, the value of SEM refers to the MID.

Results

Forty-five patients (22 men and 23 women) participated in this study. Their mean age was 44.7 years and ranged from 30 to 63 years. Twenty-seven patients received conservative periodontal care and 18 received intensive periodontal care. The baseline socio-demographic, behavioural and clinical characteristics and the prevalence of oral impacts of the whole sample and the two treatment groups are shown in Table 1. While the sample for this nested study was slightly younger, there were no differences in the baseline characteristics between the study sample and the remaining sample of the larger trial in neither the CCG nor the ICG. Forty-one of the 45 patients completed the questionnaire both at baseline and 1 month after treatment. There were no significant differences in the baseline characteristics and the generic OIDP and CS-OIDP scores between patients who were lost to follow-up and those who completed the trial ($p \geqslant 0.346$ in all cases).

Baseline and post-treatment scores are shown in Table 2. Both the generic and CS-OIDP scores 1 month after treatment were significantly lower than at baseline in the whole sample ($p = 0.007$ and 0.003, respectively), but there were no differences in the generic and CS-OIDP scores between the two treatment groups ($p = 0.431$ and 0.736,

Table 1. Baseline characteristics for the whole sample ($n = 45$), the conservative ($n = 18$) and intensive care groups ($n = 27$)

Characteristics	Whole sample	Conservative care group	Intensive care group
Mean age (SD), years	44.7 (8.1)	45.1 (6.5)	44.4 (9.1)
Sex, *n* (%)			
Women	23 (51%)	10 (56%)	13 (48%)
Men	22 (49%)	8 (44%)	14 (52%)
Education, *n* (%)			
Primary/secondary education	26 (58%)	11 (61%)	15 (56%)
Higher education	19 (42%)	7 (39%)	12 (44%)
Current smoking			
No	28 (62%)	11 (61%)	17 (63%)
Yes	17 (38%)	7 (39%)	10 (37%)
Mean number of teeth (SD)	27.0 (3.2)	26.5 (3.4)	27.3 (3.0)
Mean pocket depth (SD), mm	4.8 (0.6)	4.8 (0.7)	4.7 (0.6)
Mean number of pockets >4mm (SD)	87.3 (28.1)	87.1 (29.2)	87.4 (27.9)
Oral impacts, *n* (%)			
No (OIDP score = 0)	23 (29%)	5 (28%)	8 (30%)
Yes (OIDP score >0)	32 (71%)	13 (72%)	19 (70%)

OIDP, oral impacts on daily performances.

Table 2. Generic and condition-specific Oral Impacts on Daily Performances (OIDP) at baseline and 1 month post-treatment in the conservative and intensive care groups

Outcome measures	Conservative care group	Intensive care group	Difference (95% CI)	*p* value (between groups)
Generic OIDP score				
Mean score at baseline (SD)	7.9 (7.9)	7.6 (8.9)	0.2 (– 4.9, 5.5)	0.926
Mean score at 1 month (SD)	3.5 (4.0)	5.2 (7.7)	– 1.6 (– 5.6, 2.3)	0.410
Change (95% CI)	4.4 (0.4, 8.3)	2.5 (– 0.6, 5.5)		
p value (within group)	0.031	0.108		
CS-OIDP score				
Mean score at baseline (SD)	6.9 (6.4)	6.9 (8.0)	0.0 (– 4.6, 4.1)	0.983
Mean score at 1 month (SD)	3.3 (3.8)	4.0 (5.8)	– 0.8 (– 3.9, 2.4)	0.631
Change (95% CI)	3.6 (0.5, 6.7)	2.9 (0.1, 5.8)		
p value (within group)	0.025	0.046		

Repeated measures ANOVA was used for analysis.

respectively). When using the generic OIDP, the change scores were 4.4 (SD: 7.9, range: – 9.1 to 27.3) for the CCG and 2.5 (SD: 7.7, range: – 11.3 to 30.9) for the ICG ($p = 0.031$ and 0.108, respectively). When using the CS-OIDP, the change scores were 3.6 (SD: 6.2, range: – 9.1 to 17.8) for the CCG and 2.9 (SD: 7.2, range: – 5.8 to 23.6) for the ICG ($p = 0.025$ and 0.046, respectively).

Because there were no significant differences in the generic and CS-OIDP scores between the two treatment groups, data were pooled for the subsequent analysis. The distributions of change scores for the generic and CS-OIDP are shown in Table 3. The majority of the patients reported a better OHRQoL 1 month after treatment, 31% for the generic OIDP and 29% for the CS-OIDP reported no change, while 18% and 20%, respectively, reported deterioration in their OHRQoL. Mean OHRQoL change scores were 3.2 (SD: 7.8, range: – 11.3 to 30.9) for the generic OIDP and 3.2 (SD: 6.8, range: – 9.1 to 23.6) for the CS-OIDP (Table 4).

The different MID estimates are shown in Table 4. Overall, 38% of participants reported that their periodontal health improved a little and 49% that it improved a lot after treatment; the respective figures for improvement in their oral health were 33% (a little) and 51% (a lot). According to the anchor-based approach, the MID, calculated as the mean change score of those who reported improving a little, varied between 4.6 and 4.9 for the generic OIDP and between 5.3 and 5.7 for the CS-OIDP. In terms of the distribution-based approach, the ES and the SRM were 0.38 and 0.41 for the generic OIDP and 0.44 and 0.47 for the CS-OIDP, respectively. Furthermore,

Table 3. Distribution of change scores in the generic and condition-specific Oral Impacts on Daily Performances (OIDP) for the whole sample ($n = 45$)

Change score	Generic OIDP	CS-OIDP
– 20% to–10.1%	1 (2%)	
– 10% to–0.1%	7 (16%)	9 (20%)
0%	14 (31%)	13 (29%)
0.1% to 10%	18 (40%)	17 (38%)
10.1% to 20%	3 (7%)	5 (11%)
20.1% to 30%	1 (2%)	1 (2%)
30.1% to 40%	1 (2%)	

the SEM was 5.23 and 5.22 for the generic and CS-OIDP, respectively.

Discussion

Summary of key findings, interpretation and implications

The primary finding of this study was the estimation of the MID in the OIDP index for patients with severe generalized periodontitis receiving treatment. The MID allows interpretation of what may be meaningless OHRQoL change scores. While it is important to demonstrate improvement in OHRQoL after treatment, it is difficult to give meaning to this improvement unless it is associated with a MID. As the assessment of change is central to planning health care at both the clinical and public health perspective, determining the MID of any OHRQoL measure is a crucial feature, particularly if the measure is to be used for evaluating interventions (Osoba & King 2005).

Using different methods within both the anchor- and distribution-based approaches, the MID in the OIDP index was around five scale points. The magnitude of this change was moderate, using Cohen's benchmarks. However, what does a difference in the score of five points mean? This is 5% in the whole range of scores, but very rarely the whole range of scores is populated. To put it into perspective, slightly more than one-third of the sample had changes in OHRQoL larger than the MID, with almost all changes being in the positive expected direction.

In this study, we used both the generic and the CS-OIDP to assess changes in QoL. Previous research has shown that the CS-OIDP was better able to discriminate between groups with different oral health statuses than the

Table 4. Generic and condition-specific Oral Impacts on Daily Performances (OIDP) for the whole sample ($n = 45$): score changes over time and minimally important difference

	Generic OIDP	CS-OIDP
OIDP		
Mean score at baseline (SD)	7.7 (8.4)	6.9 (7.3)
Mean score at 1 month (SD)	4.5 (6.5)	3.7 (5.1)
Change (95% CI)	3.2 (0.9, 5.6)	3.2 (1.2, 5.2)
p value (within group)	0.007	0.003
Minimally important difference		
Anchor-based approach		
Subjective periodontal health transition	4.6 (8.2)	5.3 (7.4)
Subjective oral health transition	4.9 (8.9)	5.7 (8.0)
Distribution-based approach		
Effect size	0.38	0.44
Standardized response mean	0.41	0.47
Standard error of measurement	5.23	5.22

generic OIDP (Bernabé et al. 2009a, b) and other generic OHRQoL measures (Bernabé et al. 2008). This is important because measures able to differentiate between clinically distinct groups are also usually responsive to change (Revicki et al. 2008). Our results provide further evidence about the appropriateness of the CS-OIDP, as it had slightly higher ESs than the generic OIDP even in this severely periodontally diseased sample, where one would not expect an advantage for the CS form because almost all oral impacts would be attributed to periodontal conditions. While the generic OIDP has performed well in intervention studies (Robinson et al. 2005, Pearson et al. 2007, Berretin-Felix et al. 2008), no previous studies have used the CS-OIDP for the evaluation of clinical interventions.

This study also showed that the quality of life of periodontal patients was better 1 month after treatment compared with baseline. Although this finding is not directly comparable with other previous periodontal trials (Ozcelik et al. 2007, Aslund et al. 2008, Jowett et al. 2009), because of differences in settings and participants, the OHRQoL measures used and the timeframes used for assessment, all these studies provide evidence that periodontal disease affects quality of life and that periodontal treatment can improve it.

Moreover, both treatment groups in this study improved in terms of OHRQoL and there were no differences between them. All the patients had been referred for periodontal treatment, and all received some form of treatment. Hence, it is logical to expect improvement in OHRQoL, even with conservative care. The CCG received supragingival scaling and polishing, which although not affecting pocket depth or attachment loss, does improve gingival health and bleeding problems. The latter should improve OHRQoL. There were no significant differences in the generic and CS-OIDP scores between the ICG and CCG, although there was a slightly larger improvement in OHRQoL in the CCG rather than the ICG. These findings can be partly explained by the extensive treatment courses provided for the ICG. In many cases, the treatment involved extraction of unrestorable teeth and full recovery might take longer than the short timeframe used for evaluation in this study. Furthermore, extraction of unrestorable teeth may have contributed to the deterioration in OHRQoL. Indeed, the ICG contained the cases with the larger deterioration as well as those with the larger improvement in OHRQoL, while CCG change scores did not show a wide variation (data not shown). Availability of relevant data for a longer (e.g. 6 months) follow-up may influence the results in terms of both direction and magnitude of the differences between the two groups.

Strengths and limitations of the study

This is the first study estimating the MID for periodontal patients. Despite its importance for assessing the clinical relevance of treatment effects and informing sample size calculation for trials on OHRQoL, few studies have determined the MID for OHRQoL measures in general (Locker et al. 2004, Allen et al. 2009, John et al. 2009). This study is the first to use both a generic and CS-OHRQoL measure, using different approaches to calculate the MID. Following general recommendations (Guyatt et al. 2002, Osoba & King 2005, Revicki et al. 2006, 2008), we estimated the MID through a variety of methods and by considering both the anchor-based and distribution-based approaches. All these were used as supportive information to provide a consistent estimate on the true value of MID in the OIDP.

This study has also some limitations. First, the MID was derived from patients with severe generalized periodontitis receiving two alternative periodontal treatments. The findings may, therefore, not be generalizable to those with different levels of periodontal disease or OHRQoL. Second, the MID obtained from a single study cannot be assumed to be appropriate for all applications because it may vary according to the population sampled, the conditions under which the patients participate and the treatment evaluated (Revicki et al. 2006, Copay et al. 2007). More studies with larger and heterogeneous samples as well as comparing different periodontal treatments are required to verify and adjust, if necessary, the MID estimates reported here. Third, while there were no significant differences in the sampling distribution between the nested study and the larger trial, relevant data availability for the whole sample of the larger trial would have been welcome; however, this study does not appear to have been impeded by sampling issues in terms of answering its objectives. Fourth, although different anchor- and distribution-based approaches were used in this study, it has been recommended that the calculation of MID should also be based on clinically relevant anchors that are proximal to the construct measured and based on the understanding of the disease area and patient population (Revicki et al. 2006, 2008). However, the use of clinical anchors requires consensus among clinicians on what the smallest clinically beneficial effect might be for the disease in question (Guyatt et al. 2002). To our knowledge, no previous study has used clinical change estimates as anchors for calculating the MID in an OHRQoL measure. Further research in this area is needed in order to link clinical and subjective measures for the assessment of periodontal care.

In conclusion, this study provided an initial estimation of the MID in the generic and CS forms of the OIDP

index. The MID value was around five scale points, with slightly more than one third of the sample having improvements in OHRQoL larger than the MID. More studies are required to corroborate this MID estimate.

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Clinical Relevance

Scientific rationale for the study: OHRQoL measures are important outcomes to assess treatment effects. This study estimated the MID in the OIDP index for patients with periodontitis. The MID provides an indication of whether improvements in OHRQoL after treatment are clinically meaningful.

Principal findings: Using different approaches, the MID in the OIDP was around five scale points, with slightly more than one-third of the sample showing changes larger than this value.

Practical implications: Determining the MID in OHRQoL is crucial for evaluating interventions, since it allows interpretation of what may otherwise be meaningless change scores.